

Notice of Allowability**Application No.**

10/784,336

Applicant(s)

JORGENSEN ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/25/2008.
2. ☒ The allowed claim(s) is/are 8,9,11,12,14,15 and 17.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Ella Baio on September 2, 2008.
3. The application has been amended as follows:
4. Claims 16 and 18 are cancelled.
5. Claims 8, 9, 11-12 and 14-15 and 17 are allowed.
6. The following is an examiner's statement of reasons for allowance:
7. The claims are drawn to a method of collecting and separating blood by collecting the blood in a blood fill syringe having a blood receiving chamber forming a container, and a port through which the blood enters the chamber / container of the syringe, along with a plunger comprising a hollow plunger rod having a second port, i.e. an opening; the ports are defined by ball valves; the steps of collecting the blood in the container followed by steps of centrifuging the container comprised of the collecting chamber of the syringe with the plunger removed, such that the red blood cells component, which weigh the most, can be displaced outwardly of the other separated blood components by a soft spin in a centrifuge, the more densely packed red blood cells thus settle due to the centrifugal force of the spin and can be drawn from the port located at the needle/bottom end of the syringe; followed by a hard spin of the syringe, to separate the white blood cells, plasma and platelets, i.e. the buffy coat, from the remainder of the

blood cells comprised of plasma and platelets, being less dense, settle in the central portion of the container, then inserting a hollow plunger rod to such that less dense platelets settling at the surface of the separated blood components can be withdrawn from the opening at the top of the hollow plunger rod; in combination with the other steps recited in the claim, as detailed *infra*.

8. The subject matter not found, taught or fairly suggested in the prior art is the step of attaching a hollow plunger rod to a plunger as recited in step (f) of claim 11 and step (g) of claim 16, in combination with the other steps recited in the claims.

9. The closest prior art uncovered during examination discloses the following elements:

10. US 4,660,569 issued to Etherington: teaches a collecting a patient's blood using a needle set comprising a hollow needle and an elongated container having a first port and fitted with a movable plunger having second and third ports, then transferring the blood through the first port into the elongated container by moving the plunger away from the first port. Etherington teaches the structure of the needle set but does not teach centrifuging the container, into which blood is drawn, to separate the blood components into platelet-poor plasma, red blood cells and platelet-rich concentrate.

11. US 4,608,178 issued to Johansson et al teaches: drawing off separated red blood cells from a port located at the bottom of a container which has been centrifuged to allow the denser red blood cells to settle at the bottom of the container, and drawing off the upper layer of platelet-rich plasma from a port at the top of the container. Johansson does not teach that the container is a blood fill syringe.

12. US 3,960,139 issued to Bailey; teaches methods of collecting patients' blood, teaches a needle set comprising a hollow needle and elongated container containing an anticoagulant

therein and fitted with a movable plunger having second and third ports therein, a valve positioned within the first port, transferring the blood through the first port into the elongated container by moving the plunger away from the first port, closing the valve and attaching a plunger rod to the plunger having second and third ports. Bailey does not teach the second plunger rod having a third port and centrifuging the container to separate the platelets.

13. US 3,660,037 issued to Sokol: in Figures 1-4, teaches a method of collecting a patient's blood using a needle set and elongated container having a first port and fitted with a movable plunger having a second port, and attaching a hollow plunger rod having a third port therein the plunger, for a total of three plungers, and attachable to a valve positioned within the first port, transferring the blood through the first port into the elongated container by moving the plunger away from the first port, closing the valve and attaching a plunger rod to the plunger having second and third ports. Sokol does not teach centrifuging the container to separate the platelets.

14. US 6,193,670 B1 issued to Van Tassel et al: teaches a needle set having attached tubing and an elongated container having a first port; and centrifuging the blood in the container to obtain platelet-rich concentrate. Van Tassel does not teach a hollow plunger rod.

15. US 6,843,775 B2 issued to Hyun: teaches a blood collection and separation system comprising a needle and elongated container fitted with a movable plunger, said set having attached tubing and a fitting adapted to engage a first port in the elongated container. Hyun does not teach centrifuging the blood to separate platelet-rich concentrates.

16. US 5,102,407 issued to Carmen et al teaches that methods of separating blood components include separating red blood cells from platelets and plasma in a container by a soft spin in a centrifuge, drawing off the bottom layer of red blood cells from the container, followed

by a hard spin of the container to separate the platelets from plasma, then drawing off the upper layer of platelets and the plasma.

17. Langley et al US 5,837,150; teaches centrifuges provided with automatic level detection, i.e. automated syringe pumps load and unload syringes inserted into the apparatus, wherein the separation of the blood in the fill syringe into platelet rich plasma is automatic; operation of the centrifuge and syringe pumps is controlled by the control system hardware and software. The operator can also recover the platelet poor plasma (PPP) separated by the system. During the automated cycle, the operator is prompted by the control system via a user interface.

18. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

20. Enk (US 6,086,559) 'figures 2 and 4-8; Brannon (Re. 36, 273) figs 1 and 3-7.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
09/02/08

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761